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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------|----------------------|---------------------|------------------------|
| 10/567,872 | 05/19/2006 | Ilia Fishbein | T118/20137 | 1203 |
| 3000 | 7590 | 11/08/2007 | EXAMINER | |
| CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212 | | | | SHEN, WU CHENG WINSTON |
| ART UNIT | PAPER NUMBER | | 1632 | |
| NOTIFICATION DATE | DELIVERY MODE | | 11/08/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/567,872 | FISHBEIN ET AL. | |
| | Examiner | Art Unit | |
| | Wu-Cheng Winston Shen | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-32 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 3, 7, 8-10, drawn to a composition comprising a surface and a modified protein, wherein the modified protein is covalently bound to the surface.
- II. Claims 1, 2, 4-6, and 11-16, drawn to a composition comprising a surface and a modified protein, and *a gene transfer vector*, wherein the gene transfer vector is bound to the modified protein and the modified protein is covalently bound to the surface.
- III. Claims 17-31, drawn to a method for preparing the composition comprising a surface and a modified protein, wherein the modified protein is covalently bound to the surface, the method comprising: (a) providing a protein; (b) modifying the protein with a reagent to contain a reactive group, thereby yielding a modified protein; (c) providing a surface; (d) treating the surface with a surface modifier

comprising a linker and a functional group; (e) reacting the modified protein with the functional group on the surface in order to covalently bind the modified protein to the surface via the linker; and optionally, (f) binding the gene transfer vector to the modified protein.

- IV. Claims 17-31, drawn to a method for preparing the composition comprising a surface and a modified protein, and *a gene transfer vector*, wherein the gene transfer vector is bound to the modified protein and the modified protein is covalently bound to the surface, the method comprising: (a) providing a protein; (b) modifying the protein with a reagent to contain a reactive group, thereby yielding a modified protein; (c) providing a surface; (d) treating the surface with a surface modifier comprising a linker and a functional group; (e) reacting the modified protein with the functional group on the surface in order to covalently bind the modified protein to the surface via the linker; and optionally, (f) binding the gene transfer vector to the modified protein.
- V. Claim 32, drawn to a method of delivering a viral vector to an animal tissue, the method comprising administering to a body location in fluid communication with the animal tissue the composition comprising a surface and a modified protein, wherein the modified protein is covalently bound to the surface.
- VI. Claim 32, drawn to a method of delivering a viral vector to an animal tissue, the method comprising administering to a body location in fluid communication with the animal tissue the composition comprising a surface and a modified protein,

and *a gene transfer vector*, wherein the gene transfer vector is bound to the modified protein and the modified protein is covalently bound to the surface.

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- A) The invention has no special technical feature that defined the contribution over the prior art, or
- B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:
 - 1) A product and a special process of manufacture of said product.
 - 2) A product and a process of use of said product.
 - 3) A product, a special process of manufacture of said product, and a process of use of said product.
 - 4) A process and an apparatus specially designed to carry out said process.
 - 5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. In this case, the claims encompass multiple products and methods.

Applicant's claims encompass multiple inventions, multiple products and multiple methods, and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in all groups, as stated in claim 1, is a surface covalently bound to a modified protein. However, this common technical feature cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art. **Sharma et al.** studied the intein fusion protein consists of the modified intein fused between a target protein and an affinity tag. The affinity tag allows *the fusion protein to be immobilized on an affinity matrix* while other proteins are washed off the column. The cleavage reaction is induced on-column without elution of the bound fusion protein. The intein catalyzes the cleavage reaction at the junction between the target protein and the intein terminus in the presence of a thiol reagent such as dithiothreitol (DTT) (See Figure 1, page 1086, Sharma et al. et al., Study of protein splicing and intein-mediated peptide bond cleavage under high-cell-density conditions. *Biotechnol Prog.* 19(3): 1085-90, 2003).

4. Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Valarie Bertoglio, Ph.D./
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